

Informed Consent Form

Official Study Title: Efficacy of Eco-guided Percutaneous
Transperineal Ablation with Neodymium Laser in Patients with
Benign Prostatic Hypertrophy

R.S. 71.18

Approval Date: 04/23/2018

INFORMATION SHEET AND CONSENT DECLARATION (Non-pharmacological interventional study)

INFORMATION SHEET

Dear Sir,

In this University Hospital, a non-profit research program is planned promoted by the Department of Diagnostic Imaging entitled "Efficacy of Eco-guided Percutaneous Transperineal Ablation with Neodymium Laser in Patients with Benign Prostatic Hypertrophy". To carry out this research we need collaboration and availability of people who, like you, present the scientific requirements suitable for the evaluation that will be performed during and after the study. Before you make the decision to accept or refuse to participate, please read these pages carefully, taking all the time you need, and ask us for clarification if you do not understand or need further clarification. Furthermore, if you wish, before deciding, you can ask an opinion of your doctor or whoever you think is appropriate.

OBJECTIVES OF THE STUDY

With this study we intend to evaluate the efficacy of percutaneous ablative treatment with neodymium laser, that is the complete safety and tolerability profile in acute and in follow-up, in patients suffering from Benign Prostatic Hypertrophy, using, for the first time, as the main diagnostic tool in the follow-up multiparametric prostate MRI, which is performed in the common clinical practice due to its pathology, which allows us to evaluate with objective data the volumetric reduction of the glandular volume in the follow-up, any morphostructural gland changes and the correlation of the above advanced imaging data with clinical data ..

WHAT IS YOUR PARTICIPATION IN THE STUDIO

If you decide to participate in the Study, you will be subjected to percutaneous ablation by trans perineal pathway of benign prostatic hypertrophy with neomide lasers and local anesthesia. However, your participation does not entail any additional costs.

INVESTIGATIONS TO WHICH IT WILL BE SUBMITTED DURING THE STUDY

The study involves administering local anesthesia of the perineal region, under ultrasound guidance. 2 or 4 21G needles will be inserted, through the transperineal route and, once the prostate adenoma has been reached, an energy of about 1200 J will be delivered per fiber, with a power of 2-5 Watts. In total the treatment lasts about 30 minutes.

At the end of the treatment, 20 mg of Urbason (Cortisone) IV (if not specifically contraindicated by the patient) will be given to reduce swelling and inflammation. An antibiotic, pain relief and gastroprotective therapy will also be performed for 1 week.

Immediately after the procedure, a multiparametric prostate MRI will be performed, followed by discharge.

WHAT ARE THE RISKS ARISING FROM PARTICIPATION IN THE STUDIO

In the first hours or days after surgery, a feeling of local tension or pain may occur. Possible complications during the procedure may be related to local bleeding phenomena, subcapsular prostatic hematomas, colliquation of the treated nodule.

In the following days (7-10) pain and increased prostate volume could appear with possible evolution in pseudo-cyst (possibly to be drained), perineal pain, hematuria, hematospermia, asthenia, infection. In the following months, urethral stricture and incontinence may occur.

In the event of onset of the aforementioned complications, you can contact Prof. Guglielmo Manenti or Dr. Salvatore Marsico.

Should data become available that could influence your willingness to continue participating in the Study, you will be promptly informed.

INSURANCE POLICY

Compensation for any damage you may suffer as a result of your participation in the Study is included in the company insurance policy to cover the common clinical practice. A copy of the insurance policy is available at the clinical center for a possible consultation

WHAT ARE THE BENEFITS THAT YOU MAY RECEIVE BY ATTENDING THE STUDY

Direct participation in this study does not currently guarantee direct benefits for you, but the following direct and / or indirect benefits can be expected:

Improvement of low urinary tract symptomatology (LUTS) related to BPH (benign prostatic hypertrophy) thanks to a volumetric reduction of the prostate gland that will be evaluated with multiparametric MRI to be performed in the follow-up.

WHAT HAPPENS IF YOU DECIDE NOT TO ATTEND THE STUDY

You are free not to participate in the Study. In any case you will receive all the therapies provided for your condition, without any penalty, and the doctors will continue to follow you anyway with due care, even if there are no other therapies available.

INTERRUPTION OF THE STUDY

Your participation in the study is completely voluntary and you can withdraw at any time and for any reason without having to provide explanations, possibly communicating it to the doctor who follows you for this study.

CONFIDENTIALITY OF PERSONAL DATA

We inform you that your personal data will be collected and stored electronically and will be used exclusively for scientific research purposes.

You have the right to know what information will be stored and to update or change incorrect data. Access to these data will be protected by the Investigator (the doctor who follows you during the Study). Regulatory authorities (Ministry of Health), medical staff, monitoring and verification of the correct procedures (Independent Ethics Committee) will be able to inspect the archive without the possibility of tracing back to your personal identity.

The results of the study in which it participates may be published but your identity will always remain secret, in full compliance with the legislation in force in Italy on the protection of personal data D.Lgs.196 dated 30.06.2003.

INFORMATION ABOUT THE RESULTS OF THE STUDY

If you request it at the end of the study, the results of the study in general and in particular those that concern you if they are available will be communicated to you.

FURTHER INFORMATION

The proposed Study Protocol was drafted in accordance with the "Rules of Good Clinical Practice" of the European Union and the current revision of the Helsinki Declaration and was approved by the Independent Ethics Committee at this University Hospital. You can report any fact to the Committee that it deems appropriate to highlight, which concerns you, in relation to the Study.

DECLARATION OF CONSENT

I, the undersigned: _____
born in _____ the _____, residing in _____
on _____,

DECLARE

- to have received comprehensive explanations regarding my participation in the Study "Efficacy of Eco-guided Percutaneous Transperineal Ablation with Neodymium Laser in Patients with Benign Prostatic Hypertrophy". as reported in the attached information sheet, a copy of which was delivered to me sufficiently in advance;
- to have been able to discuss these explanations; to have been able to ask all the questions that I deemed necessary and to have received satisfactory answers, to therefore be aware of all the possible risks and benefits that may derive from my participation in the Study;
- to be aware that at any time and for any reason I will be able to withdraw from the Study, and in any case be treated with the ordinary therapies for the illness of which I suffer, without the obligation to motivate the decision, unless it derives from the appearance of disorders or unwanted effects, in the event I undertake to contact the doctor who follows me during the study promptly;
- that my participation is free, not influenced by promises of money or other benefits, nor by obligations of gratitude or friendship and / or kinship towards the doctor who proposes the study;
- to have been informed of my right to have free access to the documentation relating to the Study (insurance, clinical-scientific, drug-therapeutic), and to the evaluation expressed by the Independent Ethics Committee;
- to authorize the use and disclosure, anonymously, for scientific and administrative purposes only and in compliance with the regulations in force on the protection of confidentiality, of the results of the Study, including the clinical data concerning me, in full compliance with current legislation in Italy on the protection of personal data (Legislative Decree 196/2003);
- to have been informed that the trial is covered by the Insurance Policy _____
- to freely accept, therefore, to participate in the Study, having fully understood the meaning of my participation having understood the risks and benefits involved.

Date Signature of the patient

Date Signature of the investigating doctor

Signature of the investigator
doctor (in block letters)

INFORMATION AND EXHIBITION OF CONSENT TO THE PROCESSING OF PERSONAL DATA

Data controllers and related purposes

The U.O.C. of Diagnostic Imaging of the PTV Policlinico Tor Vergata Foundation, in accordance with the responsibilities provided by the norms of good clinical practice (Legislative Decree 211/2003), will treat your personal data, in particular those concerning health, exclusively to the extent that they are indispensable in relation to the objective of the study.

To this end, the data indicated will be collected in full compliance with the legislation in force in Italy on the protection of personal data (Legislative Decree 196/2003).

The processing of personal data is essential for the conduct of the study: the refusal to grant them will not allow you to participate.

Nature of the data

The doctor who will follow you in the study will identify you with a code: the data relating to you collected during the study, with the exception of your name, will be recorded, processed and stored together with this code, your date of birth and gender. The Study Promoter Experimentation Center will process your personal data, both generic (name, surname, date of birth, etc.) and your health status, anonymously and exclusively according to the implementation of the research program. Only the doctor and his authorized collaborators can link this code to your name.

Processing methods

The data, processed using electronic or electronic means, will be disseminated only in strictly anonymous form, for example through scientific publications, statistics and scientific conferences. Your participation in the study implies that, in accordance with current legislation, the staff of the Ethics Committee and the Italian health authorities will be able to know the data concerning you, also contained in your original clinical documentation, in such a way as to guarantee the confidentiality of your identity.

Exercise of rights

You can exercise your rights pursuant to art. 7 of the Privacy Code (Legislative Decree 196/2003) (eg access to your personal data, integrate them, update them, rectify them, oppose their processing for legitimate reasons, etc.). You can interrupt your participation in the study at any time and without giving any justification: in this case, no further data concerning you will be collected, without prejudice to the use of those already collected to determine, without altering them, the results of the research, unless you explicitly request that this does not happen.

Consent

By signing this form I consent to the processing of my personal data for research purposes within the limits and in the manner indicated in the information provided to me by this document.

Name and surname of the person concerned (in block capitals) _____

Signature of the interested party _____

Date _____